IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GILEAD SCIENCES, INC., Plaintiff, v. APOTEX, INC., LUPIN LIMITED, LAURUS LABS LIMITED, SHILPA MEDICARE LIMITED, SUNSHINE LAKE PHARMA CO., LTD., NATCO PHARMA LIMITED, CIPLA LIMITED, MACLEODS PHARMACEUTICALS LTD., HETERO USA INC., HETERO LABS LIMITED UNIT-V, AND HETERO LABS LIMITED, Defendants.	C.A. No. 20-00189 (MN) [redacted] REDACTED

LETTER TO THE HONORABLE MARYELLEN NOREIKA FROM GRAYSON P. SUNDERMEIR REGARDING DISCOVERY DISPUTE

Douglas E. McCann (#3852)
Grayson P. Sundermeir (#6517)
FISH & RICHARDSON P.C.
222 Delaware Avenue, 17th Floor
Wilmington, DE 19801
(302) 652-5070
Email: dmccann@fr.com; sundermeir@fr.com

Dated: January 26, 2021

cc: Counsel of Record – via Electronic Mail

Dear Judge Noreika:

Plaintiff Gilead brings this dispute as a result of Defendant Shilpa's refusal to provide samples of the active pharmaceutical ingredient ("API") in its ANDA product. There should be no reason to burden the Court with this dispute. Each of the other eight Defendants in this case have produced, or agreed to produce, the API for their respective products. And, even Shilpa does not dispute the relevance of the API to issues in the case or argue that producing it is not proportional. Instead, Shilpa has raised three baseless reasons for its refusal to provide discovery, asserting that: (1) Gilead's request for Shilpa's API is untimely, (2) Shilpa will not provide its API until Gilead agrees not to use it for any purpose related to unasserted claims, and (3) Shilpa will not provide its API unless Gilead agrees to a date by which it will assert any additional patent claims. All of these reasons should be rejected by the Court.

I. Background

This is a Hatch-Waxman case related to Gilead's transformative HIV products, Vemlidy®, Descovy®, and Odefsey®. All three products include the active ingredient tenofovir alafenamide fumarate, or TAF for short, the present-day gold standard in HIV/HBV therapy. Shilpa filed an ANDA seeking approval for a generic version of one of those three products, Vemlidy®, prior to the expiration of two of Gilead's Orange Book-listed patents. (*See* D.I. 1 at ¶¶ 192-200.) On February 7, 2020, Gilead initiated this action against Shilpa for infringement of those two patents, which cover the particular pharmaceutical form of TAF in Vemlidy®, called TAF hemifumarate. (*See id*. at ¶¶ 192-200, 940-1005.)

On October 7, 2020, Gilead served Shilpa with its Request for Production No. 59, which sought "[t]wenty-five grams of the Tenofovir Alafenamide Fumarate drug substances that Defendant will incorporate or has incorporated into its VEMLIDY ANDA Product." (*See* Ex. A (Gilead's RFP 59).) Shilpa's response on November 6, 2020 stated that Shilpa had produced samples of its ANDA product (not the API) and that it was otherwise willing to meet and confer with Gilead regarding the Request. (*See* Ex. B (Shilpa's Response to RFP 59) at 11.)

The parties first met and conferred on November 19, 2020. (*See* Ex. C (Email chain re "Shilpa's response to Gilead's RFP No. 59") at 4-6.) During this discussion, counsel for Shilpa did not object to Gilead's request on the basis of relevance or any undue burden in providing its API. Quite the opposite; Shilpa initially indicated that it would produce the API, sending a series of emails confirming the quantity available, storage requirements and shipping costs, and estimating the time period to ship the samples. (*See id*. at 1-5.) On December 2, Gilead wrote to Shilpa to confirm when Shilpa would produce samples of its API. (*Id*. at 1.)

Later, however, Shilpa reversed course. During a December 8 discussion with Gilead on a separate issue, Shilpa surprisingly *refused to produce its API*, despite its relevance, based on three concerns that it raised for the first time. First, Shilpa oddly suggested that Gilead's request was untimely, even though Gilead served it over a year before the close of fact discovery. (*See* Ex. D (Email chain re "Today's Meet and Confer dial-in") at 5-6.) Second, purported delay aside, Shilpa said that it would not produce the API unless Gilead agreed not use Shilpa's drug substance with respect to any unasserted patent claims. (*Id*.) Finally, Shilpa

refused to produce the API unless Gilead committed to a date certain by which it will assert any new patent claims. (*Id*.) On that call and in follow-up correspondence, Gilead asked Shilpa for its legal basis for shielding discovery based on these objections. (*See id*. at 1-6.) Shilpa never provided one.

II. Shilpa's API Should be Produced Because it is Relevant at Least to Infringement and its Production is not Unduly Burdensome

Shilpa does not dispute that its API is relevant to Gilead's claims of infringement. Nor could it. Claim 1 of asserted U.S. Patent No. 8,754,065 claims "tenofovir alafenamide hemifumarate." (*See* D.I. 1, Ex. C.) Gilead asserts that Shilpa infringes claim 1 (among others) because the API in its proposed ANDA product includes just what the claim says, tenofovir alafenamide hemifumarate. Dependent claims of the '065 patent recite specific characteristics of compositions including TAF hemifumarate, methods of making it, and methods of using it. (*See id*.) Shilpa has served an interrogatory response contesting infringement of claim 1 and all other asserted claims of the '065 patent. (*See* Ex. E (Shilpa's Nov. 19, 2020 Supp. Response to Interrogatory 6) at 6-14.)

This Court (and others) have recognized that an ANDA Defendant's API is properly discoverable when it is relevant to issues in dispute, including infringement. *See Astellas US LLC v. Apotex, Inc.*, C.A. 18-1675-CFC-CJB, D.I. 247 at 2-3 (D. Del. April 13, 2020); *see also id*., D.I. 550 at 1-3 (D. Del. Nov. 4, 2020); *see, e.g., Illumina Inc. v. BGI Genomics Co., Ltd.*, 2020 WL 7047708, at *5-*6 (N.D. Cal. Dec. 1, 2020). For its part, Shilpa has not disputed that its API is relevant to infringement. Shilpa also has not articulated any undue burden in producing its API. Indeed, as the correspondence between the parties evidences, Shilpa has API readily available and even identified shipping conditions and pricing. (*See* Ex. C at 1-5.) There is thus no basis for Shilpa to refuse production. *See* Fed. R. Civ. P. 26(b).

All of the excuses Shilpa has provided for refusing to produce its API lack merit. First, Shilpa cannot argue with a straight face that Gilead's request was "too late." Gilead served its request for Shilpa's API in early October 2021, seven months before the deadline for substantial completion of document production and over a year before the close of fact discovery. (*See* D.I. 83 at 13.) Shilpa has not provided any basis for the premise that a discovery request, served over one year before the close of fact discovery, is untimely. *C.f. Banner v. Dept. of Health and Human Services Division for the Visually Impaired*, 2018 WL 1377095, at *7 (D. Del. Mar. 19, 2018) (finding discovery requests untimely when served one day before the fact discovery deadline).

Shilpa's attempt to condition its production on Gilead's agreement not to use the API in determining whether to assert additional patent claims is also unfounded. There is no restriction in the Protective Order preventing the parties from using discovery material for unasserted patent claims. And, Shilpa never asked for such a restriction. In any event, such a restriction would not be appropriate, particularly in a Hatch-Waxman case where there is no marketed accused product. *See Hoffmann-La Roche Inc. v. Invamed*, 213 F.3d 1359, 1363-64 (Fed. Cir. 2000) (permitting Plaintiff in a Hatch-Waxman to "resort to the judicial process and the aid of discovery … to confirm their belief and present to the Court evidence that each and

every defendant infringes one or more claims[.]"). Moreover, Shilpa has not provided any explanation why it's API should be treated differently than other discovery materials in this case, including samples of its complete ANDA product, which Shilpa produced without complaint.

Finally, Shilpa cannot hold its API hostage unless Gilead agrees to a date certain by which it will assert additional claims of the patents-in-suit. Shilpa's request – which essentially seeks final infringement contentions – is inconsistent with case law, Local Rules, and the Scheduling Order (D.I. 83). *See Lambda Optical Solutions, LLC v. Alcatel-Lucent USA Inc.*, 2013 WL 1776104 at *3-*4 (D. Del. Apr. 17, 2013) (holding plaintiff was permitted to supplement infringement contentions two months before the close of fact discovery); *see also* District of Delaware Default Standard for Discovery, Including Discovery of Electronically Stored Information at 4, n.3 (permitting supplementation of initial infringement contentions). Moreover, if Shilpa wanted a date certain by which Gilead would identify final asserted claims, Shilpa could have asked for such a date in the Scheduling Order. Shilpa did not. Regardless, such a deadline any time soon in this case would make little sense. The Court has yet to construe the claims, and fact discovery has barely begun. Indeed, Shilpa has ***not produced a single document*** beyond the core technical documents required under the Delaware Default Standard for Discovery. Shilpa's attempt to shield relevant discovery to coerce Gilead into prematurely serving final infringement contentions is improper and should be rejected.[1]

Ultimately, it is undisputed that the material Gilead seeks is relevant and not unduly burdensome for Shilpa to produce. Because Shilpa offers no credible basis to shield this material from discovery, Gilead respectfully requests the Court order Shilpa to provide its API to Gilead no later than February 19, 2021.

Respectfully submitted,

/s/ Grayson P. Sundermeir

Grayson P. Sundermeir (No. 6517)

cc: Counsel of Record – via Electronic Mail

[1] Gilead has repeatedly conveyed to Shilpa that it will work expeditiously to identify any additional asserted patent claims. (*See, e.g.*, Ex. C at 1-4; Ex. D at 5-6.) Ironically, to the extent Shilpa believes Gilead will use Shilpa's API to aid in that determination, Shilpa's refusal to produce its API and the delay caused by having to bring this issue before the Court has only slowed that process down.